

Appl. No. : 09/218,213  
Filed : December 22, 1998

#### REMARKS

Claims 2-51 are pending in the present application and stand rejected under 35 U.S.C. § 112, second paragraph. Further, the United States Patent and Trademark Office (PTO) has required restriction of the pending claims under 35 U.S.C. § 121. These matters are addressed below.

#### Continuation data

The United States Patent and Trademark Office (PTO) has requested an update concerning that status of all continuation data referred to in the specification. In response, Applicants have amended the specification to recite the present known state of the continuation data.

#### Claims 2-51 distinctly claim the subject matter regarded by Applicants as their invention

The PTO has rejected claims 2-51 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Specifically, the PTO has objected to three phrases, "plurality of perforated structures," "predetermined volume," and "fluorochemical continuous phase."

The PTO has rejected claims 2-51 under 35 U.S.C. § 112, second paragraph, in part, based upon the phrase, "a plurality of perforated structures." The basis for this rejection is not clear from the office action because the quoted phrase is absent from all of the pending claims. Applicants believe that the PTO sought to reject the phrase, "a plurality of perforated microstructures," and direct their response to this phrase.

During prosecution the PTO must interpret the pending claims in the broadest reasonable manner consistent with the specification. In re Prater, 415 F.2d 1393, 1404-05 (CCPA 1969). Assuming that the phrase "plurality of perforated microstructures," is the source of the pending rejection, Applicants respectfully submit that this phrase should be given its broadest possible interpretation. In order to make this interpretation, Applicants direct the PTO to the specification, for example, at page 6, lines 11-16 and page 14, line 8 to page 32, line 8 for a description of perforated microstructures.

The perforated nature of the particles recited in the pending claims provides for the

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superior functionality of the compositions described in the specification. In one nonlimiting hypothesis, the perforated, porous particles of the pending claims show increased stability in solution because of the presence of pores in the particles. The characteristic of the perforated particles permitting suspension medium to permeate the particles, serves to reduce the van der Waals attractive forces that cause creaming and flocculation in other, nonperforated particles. (See Specification at page 14, lines 8-18).

It is axiomatic that an applicant for a patent is free to be his or her own lexicographer. Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558 (Fed. Cir. 1990). As noted above, the specification defines and describes the perforated microstructures of the pending claims. In view of this disclosure, Applicants respectfully request the withdrawal of the rejection with respect to the phrase, "perforated microstructures."

The next phrase rejected by the PTO was the phrase "predetermined volume." Applicants submit that this phrase is clear and has a particular meaning within the context of the specification as a whole. Accordingly, Applicants request withdrawal of this rejection.

The last phrase rejected by the PTO was the phrase "fluorochemical continuous phase" because "fluorochemicals" are alleged not to have been specified nor would they be apparent to one of ordinary skill in the art. Applicants respectfully disagree with this rejection.

Fluorochemicals are defined at page 13, lines 6-19 of the specification. The specification teaches, "a nonaqueous continuous phase that preferably comprises a fluorinated compound (i.e. a fluorochemical, fluorocarbon or perfluorocarbon)." (Page 13, lines 6-7). From the teaching of the specification it would be clear to one of ordinary skill in that art that a fluorochemical can be any fluorinated compound that otherwise satisfies the other requirements of the invention. In view of the clear description of the term fluorochemicals, Applicants respectfully request the withdrawal of the rejection based on this term.

#### Response to Restriction Requirement

The PTO has restricted the pending claims into four groups of claims. Group I comprises Claims 2-12, which are drawn to a delivery method, classified in classes 424/514, and in a variety of subclasses. Group II comprises Claims 13-29, which are drawn to a method of stabilizing a respiratory dispersion, classified in class 514, and subclass 937. Group III comprises Claims 30-38, which are drawn to a respiratory dispersion, classified in class 424,

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subclass 45. Group IV comprises Claims 39-51, which are drawn to an inhalation apparatus, classified in class 128, subclass 200.11.

In response to the requirement for restriction, Applicants elect, with traverse, to prosecute the claims of Group I, claims drawn to a delivery method. In making the restriction requirement, the Examiner has stated that Groups I and IV are related as process and apparatus for its use and has required restriction because the process as claimed can be practiced by another and materially different apparatus such as a manual aerosol delivery device. The restriction requirement is traversed for the reasons below.

Applicants respectfully submit that the method as claimed in claim 2 can not be practiced with another and materially different apparatus. Claim 2 specifically recites nebulizing the respiratory dispersion with a nebulizer to provide an aerosolized medicament. Claim 39 also recites a nebulizer. Thus, Applicants respectfully submit that the restriction requirement as set forth by the Examiner is in error and requests that Groups I and IV be examined together.

Furthermore, Applicants respectfully submit that Group III, claims 30-38 should also be considered with claims 2-12 and 39-51 of Groups I and IV. Claim 30 recites a stable respiratory dispersion for use in a nebulizer. Thus, each of independent claims 2, 30, and 39 as claimed are each specific to methods, compositions, and devices for administering bioactive agents by nebulization. For purposes of responding to the outstanding restriction requirement, Applicants have elected the claims in Group I as set forth by the Examiner, but respectfully submits that the claims of Group I should be examined at the same time with the claims of Groups III and IV for the above reasons. Reconsideration of the restriction requirement is respectfully requested.

No fees are seen as being necessary in connection with this Response. However, the Commissioner is authorized to charge any fees in connection with this paper to Deposit Account No. 11-1410. A copy of this response is attached for this purpose.

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### CONCLUSION

Applicants believe that all the pending claims are presently in condition for allowance. However, the Examiner is invited to telephone the undersigned attorney at the number below if it is believed that this will expedite prosecution of the present application.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 

James J. Mullen III, Ph.D.  
Registration No. 44,957  
Attorney of Record  
620 Newport Center Drive  
Sixteenth Floor  
Newport Beach, CA 92660  
(619) 235-8550

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